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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,575	01/16/2002	Nishizumi Nishimuta	018995-452	4939

7590

07/16/2003

Platon N. Mandros  
BURNS, DOANE, SWECKER & MATHIS, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/16/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/046,575

Applicant(s)

NISHIMUTA ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7,8,15 and 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,9-14,16 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants affirmation on the election of species without traverse is acknowledged. Applicant's election includes tinidazole, atopic dermatitis and combination with steroid as the species of each category. The readable claims are 1-3, 6, 9-14, 16, 31 are presented for the examination and the non-elected claims 4-5, 7-8, 15, 17-30 are withdrawn from the consideration.
2. Therefore the restriction requirement is maintained and made FINAL.

### ***Information Disclosure Statement***

3. Applicant's information disclosure statements (see paper no. 2-4) have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 6, 9-14 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or ameliorating specific exemplified skin diseases using nitroimidazole derivatives, does not reasonably provide enablement for treating or ameliorating all the skin diseases by nitroimidazole derivatives. For example, the specification teaches that few specific skin disorders such as atopic dermatitis can be treated by nitroimidazole derivatives, but not all skin diseases(e.g. skin cancers). Since each skin disorder has different causative factors,

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symptomology and manifestations, and is originated by different etiology and pathology, it is conventional knowledge that the treatment or selection of therapeutic modality should be selective according to the types of diseases.

Secondly, claims 1-3, 6, 9-14, 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or ameliorating skin diseases such as atopic dermatitis, does not reasonably provide enablement for prophylactically treating all skin diseases. It is art recognized fact that not all the skin diseases can be prophylactically treatable( preventable), even if, few skin diseases are considered to be preventable, not all the skin diseases are preventable. Furthermore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to use compounds of formula(I) as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975 .

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6, 9-14, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/027960.

The claims are drawn to a method of treating skin diseases using an effective topical application of nitroimidazole derivative(e.g. tinidazole(elected species). WO'960 teaches a viscous hydrogel topical composition for treating inflamed skin, comprising an antimicrobially active nitroimidazole drug, see abstract. Especially, WO'960 teaches that tinidazole (0.75%) as an effective species can be used in the topical treatment of certain dermatological diseases such as rosacea and eczema, see page 1, lines 12-15 and example 1.

Thus, all the critical elements are taught by the cited reference and the claims are anticipated.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 12-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al(WO98/27960) in view of Miller et al (1980, abstract only) and Fleischer (1999, abstract only).

The teaching of WO'960 is mentioned immediately above in 102 rejection(supra). WO'960 teaches a treatment of inflamed skin diseases such as eczema using a therapeutically effective amount of tinidazole via topical application.

Applicant's claim differs because claim 16 requires atopic dermatitis.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify and extend the teaching of WO'960 to include atopic dermatitis as taught in Fleischer(1999) and Miller(1980).

Fleischer(1999) teaches a treatment of atopic dermatitis which is a chronic and relapsing form of eczema where immune regulation appears to play an important role in the cause of atopic dermatitis and immunosuppressants are effectively used in the treatment of atopic dermatitis, see entire abstract.

Miller(1980) teaches tinidazole as an effective immunosuppressant in vivo, see abstract.

One would have been motivated to make such modification because it is always to desired to have more therapeutic modalities Especially, the active drug is already proven for its efficacy, for instance, a topical immunosuppressant therapy would be even more desirable and advantageous due to its reduced side effects. One would have been motivated to do so, with reasonable expectation of success, because tinidazole is already proven for its effectiveness against eczema(WO'960) in this case. Thus, one

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would have expected a effective treatment of atopic dermatitis, chronic, relapsed form of eczema, by applying a topical application of tinidazole.

As to claims 12-13, combination drug regimen is conventional knowledge in the treatment of atopic dermatitis as evidenced by numerous documents(see PTO-892). Especially, it is well known that steroid is effective therapeutic modality used in combination drug therapy for atopic dermatitis treatment. Thus, it would have been obvious to add steroid to enhance the therapeutic efficacy as suggested by numerous documents available in the art and the use of subtherapeutic dose is also conventional knowledge when the combination drug therapy is used. One would have been motivated to do so, with reasonable expectation of success, because each drug uses different biological pathway where additive effect can be maximized while the side effect could be reduced as well as the doses required for the successful treatment.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

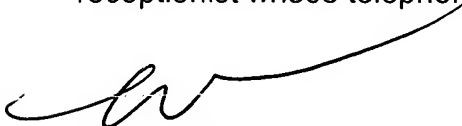
### ***Conclusion***

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel

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can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
July 14, 2003  
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